

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SIMILARITY ACTION FOR 91234-GG

June 23, 2017

Subject: A117.02
EPA File Symbol: 91234-GG
DP Barcode: 440466
Action Code: R300
PC Code: 097601 (Propargite: 9.1%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Through: P.V. Shah, Ph.D., Branch Chief
CITAB
Registration Division (7505P)

To: Richard Gebken, RM 10
Invertebrate-Vertebrate Branch 2
Registration Division (7505P)

Applicant: ATTICUS, LLC

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
097601 Propargite (Sulfurous acid, 2-[4-(1,1-dimethyl-ethyl) phenoxy] Cyclohexyl-2-propynyl ester)*.....	69.6%
<u>Other Ingredients:</u>	30.4%
TOTAL:	100.0%

*Contains 6 lbs active ingredient per gallon. Contains petroleum distillates.

ACTION REQUESTED: "Is 91234-GG similar to 400-154?"

BACKGROUND: The material available to CITAB includes a CSF (dated May 4, 2017), a data matrix (dated May 12, 2017) available from Documentum, and a label (proposed signal word:

DANGER), available from Documentum. From the data matrix the registrant is using cite-all to satisfy the acute toxicity data requirements. From the application for registration (EPA Form 8570-1) the registrant is stating that 91234-GG is similar or identical in composition and labeling to EPA Reg. Nos. 400-154, 400-89 and 400-104.

COMMENTS AND RECOMMENDATIONS:

1. An examination of the labels for EPA Reg. Nos. 400-89 (Propargite: 69.2%), 400-104 (Propargite: 73.6%) and 400-154 (Propargite: 69.6%) indicates they all have the signal word DANGER. From the precautionary labeling statements ("Causes irreversible eye damage"), EPA Reg. Nos. 400-104 and 400-154 are in toxicity category I for eye irritation potential, while EPA Reg. No. 400-89 ("Causes substantial but temporary eye injury") is in toxicity category II for eye exposure. However, all 3 cited products are in toxicity category I for dermal irritation (all have "Corrosive" and all have "Causes skin burns").
2. The following is the acute toxicity profile of EPA Reg. No. 400-89, from a TRB review (TXR 5001032) dated October 16, 1997:

Acute oral LD ₅₀ (rat)	II ^a	MRID 43668201	Acceptable
Acute dermal LD ₅₀ (rat)	III	MRID 43668202	Acceptable
Acute inhalation LC ₅₀ (rat)	III	MRID 43668203	Acceptable
Eye irritation (rabbit)	II	MRID 43668204	Acceptable
Skin irritation (rabbit)	I	MRID 43684601	Acceptable
Dermal sensitizer (g. pig)	Positive ^b	MRID 43668205	Acceptable

^aBased on an oral LD₅₀ of 428 mg/kg in ♀; consistent with label statement: "May be fatal if swallowed."

^bConsistent with statement on label: "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

3. The following is the acute toxicity profile of EPA Reg. No. 400-104 from a PRS review (TXR 5002570) dated December 6, 1994 and a subsequent PRS review dated December 30, 1996:

Acute oral LD ₅₀ (rat)	III	MRID 42766101	Acceptable
Acute dermal LD ₅₀ (rat)	IV	MRID 42766102	Acceptable
Acute inhalation LC ₅₀ (rat)	III	MRID 42766103	Acceptable
Eye irritation (rabbit)	I	MRID 42766104	Acceptable
Skin irritation (rabbit)	I	MRID 42766105	Acceptable
Dermal sensitizer (g. pig)	Negative	MRID 42766106	Acceptable

4. The following is the acute toxicity profile of EPA Reg. No. 400-154 from a TRB review (TXR 5001021) dated September 25, 1997:

Acute oral LD ₅₀ (rat)	III	MRID 43668401	Acceptable
Acute dermal LD ₅₀ (rat)	III	MRID 43668402	Acceptable
Acute inhalation LC ₅₀ (rat)	II	MRID 43668403	Acceptable
Eye irritation (rabbit)	I ^a	MRID 43668404	Acceptable
Skin irritation (rabbit)	I	MRID 43668405	Acceptable
Dermal sensitizer (g. pig)	Negative	MRID 43668406	Acceptable

^aOriginally assigned to toxicity category II (TXR 5001021) but positive for conjunctival effects (redness score of 2) in 2/2 rabbits on day 24, with clearing by day 28. Tox. Category I is consistent with "...irritation persisting for more than 21 days." Statement on label of 400-154 indicates Category I.

5. After a review and comparison of the CSFs for 400-89, 400-104 and 400-154 with the proposed CSF for 91234-GG, CITAB concludes that the Agency can accept a similarity claim to the cited products, with an acute toxicity profile based on a worst-case scenario, as indicated below:

Acute oral LD ₅₀ (rat)	II	MRID 43668201	Cited (400-89)
Acute dermal LD ₅₀ (rat)	III	MRID 43668202	Cited (400-89)
Acute inhalation LC ₅₀ (rat)	II	MRID 43668403	Cited (400-154)
Eye irritation (rabbit)	I	MRID 43668204	Cited (400-89)
Skin irritation (rabbit)	I	MRID 43684601	Cited (400-89)
Dermal sensitizer (g. pig)	Positive	MRID 43668205	Cited (400-89)

6. Based on the acute toxicity profile above, with additional information from the CSF, the following is the precautionary and first aid labeling for 91234-GG, as obtained from the Label Review System:

PRODUCT ID #: 091234-00033

PRODUCT NAME: A117.02

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

SPANISH SIGNAL WORD: PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Contains Petroleum Distillate.

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

Corrosive. Causes skin burns. Causes irreversible eye damage. May be fatal if inhaled. May be fatal if swallowed. Harmful if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, and chemical-resistant gloves (such as Barrier Laminate, Butyl Rubber, Nitrile Rubber, Viton). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Do not breathe spray mist.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

For handling activities, use a NIOSH approved respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. For overhead exposure wear chemical-resistant headgear. When cleaning equipment wear a chemical-resistant apron.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If swallowed:

- Immediately call a poison control center or doctor.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give **any** liquid to the person.
- Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Primary Skin Irritant toxicity, Primary Eye Irritant toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

NOTE TO PHYSICIAN: May pose an aspiration pneumonia hazard. Contains petroleum distillate.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

7. The first aid statement for If On Skin (Toxicity Category I) should precede the first aid statement for If Inhaled (Toxicity Category II).
8. The proposed label for 91234-GG includes (under PRECAUTIONARY STATEMENTS) a reference to [glove] selection category E. From Chapter 10 page 9 of the Label Review Manual: "The EPA Chemical Resistance Category Selection Chart for Gloves should never be placed or referenced on the product label; it is intended for EPA and registrant guidance only."
9. The acute toxicity data requirements for the registration of 91234-GG have been satisfied by similarity and cite-all.